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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,631	01/16/2003	Charlotte Hauser- Funke	KGB	3848

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EXAMINER	
KELLY, ROBERT M	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,631	HAUSER- FUNKE, CHARLOTTE	
	Examiner	Art Unit	
	Robert M Kelly	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-9, drawn to the use of a nucleic acid construct comprising at least one HRE and a transgene which are not functionally linked and a hormone-hormone receptor complex to prepare a gene transfer agent.

Group II, claim(s) 10-21, drawn to the use of a nucleic acid construct comprising at least one HRE, a transgene, and a gene-expression regulatory element, which HRE and transgene are not functionally linked, and a hormone-hormone receptor complex to prepare a gene transfer agent, and pharaceutical compositions derived from the agent prepared.

Group III, claim(s) 10 and 12-21, drawn to the use of a nucleic acid construct comprising at least one HRE, a transgene, and a genetic maintenance element, which HRE and transgene are not functionally linked, and a hormone-hormone receptor complex to prepare a gene transfer agent, and pharaceutical compositions derived from the agent prepared.

Group IV, claim(s) 10 and 12-21, drawn to the use of a nucleic acid construct comprising at least one HRE, a transgene, and a marker gene, which HRE and transgene are not functionally linked, and a hormone-hormone receptor complex to prepare a gene transfer agent, and pharaceutical compositions derived from the agent prepared.

Group V, claim(s) 22-25, drawn to the use of a nucleic acid construct comprising at least one HRE and transgene encoding a blood-clotting factor, wherein the transgene and blood-clotting factor are not functionally linked, and vectors comprising the nucleic acid construct.

Group VI, claim(s) 26, drawn to a composition of matter comprising a nucleic acid construct comprising at least one HRE and a transgene encoding a blood clotting factor, and/or a vector comprising the construct, which vector comprises an HRE coupled to a hormone-hormone receptor complex.

Group VII, claim(s) 27, drawn to a method of preparing a composition of matter comprising admixing a nucleic acid construct with a hormone receptor and hormone.

Group VIII, claim(s) 28-33, drawn to a method for gene transfer comprising administration of an agent or pharmaceutical composition comprising the agent to an organism or cellular system.

Group IX, claim(s) 34-40 and 47-49, drawn to the use of a nucleic acid construct comprising at least one HRE and a transgene which are functionally linked and a hormone-hormone receptor complex to prepare an agent for treating hemophilia, and a method of gene transfer of such agents into an organism or cellular system.

Group X, claim(s) 41-49, drawn to the use of a nucleic acid construct comprising at least one HRE, a transgene, and a gene-expression regulatory element, which HRE and transgene are functionally linked, and a hormone-hormone receptor complex to prepare an agent for treating hemophilia, and a method of gene transfer of such agents into an organism or cellular system.

Group XI, claim(s) 41 and 43-49, drawn to the use of a nucleic acid construct comprising at least one HRE, a transgene, and a genetic maintenance element, which HRE and transgene are functionally linked, and a hormone-hormone receptor complex to prepare an agent for treating hemophilia, and a method of gene transfer of such agents into an organism or cellular system.

Group XII, claim(s) 41 and 43-49, drawn to the use of a nucleic acid construct comprising at least one HRE, a transgene, and a marker gene, which HRE and transgene are functionally linked, and a hormone-hormone receptor complex to prepare an agent for treating hemophilia, and a method of gene transfer of such agents into an organism or cellular system.

The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature shared by the groups is the use of a nucleic acid construct with an HRE and gene-encoding sequence, a hormone and a hormone receptor. U.S. Patent No. 5,783,681 to Matusik, filed 8 March 1995, patented 21 July 1998 teaches a CAT transgene, an HRE within plasmid pPH 1.4, which contains other, non-functionally-linked transgenes (col. 6, last paragraph), and their binding to an androgen-androgen receptor complex (hormone-hormone receptor) (col, 8, line 11-col. 12, lines 17). Hence, the invention of group I contributes nothing over the art. Groups II-XII require additional gene-expression regulatory elements, genetic maintenance elements, marker genes, bloot clotting factors, coupling the HRE to the hormone-hormone receptor complex, mixing constructs with other elements, administration of complexes to organisms, functionally-linked transgenes and HREs, and the functionally linked species further requiring additional regulatory elements, additional maintenance elements, and additional marker genes. Hence, because each of these groups require a special technical feature not required for the other groups, groups I-XII do not relate to a single general inventive concept.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(i) Claims 2-4 and 7-8 lists 16 distinct species and SEQ ID NOs of transgene;

(ii) Claims 10 and 41 each list three species of gene-expression regulatory element: promoter, enhancer, and silencer sequences; and three species of genetic maintenance element: origin of replication, integrational sequences, and switch sequences;

(iii) Claims 15 and 46 each list three species of progesterone receptor;

(iv) Claims 19-20 list two blood-clotting factors;

(v) Claim 30 lists two blood clotting factors;

(vi) Claims 32-33 list two forms of hemophilia; and

(vii) Claims 35 and 38-39 list four blood clotting factors.

Applicant is required, in reply to this action, to elect a single species in each instance to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. Applicant is required to choose species consistent with any other choice made, with respect to any group chosen. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 10, 22, 26, 27, 28, 34, and 41.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each of the species contains distinct, unrelated structure, which, provide unique function. For example, each of the genera of transgene has different effects, e.g., a blood clotting factor would require structure to interact with the blood clotting pathways of an organism, but a hormone would be required to interact with cellular components to stimulate different pathways, not those that cause clotting; hence, they have different structural requirements. Furthermore, each of these would require different structure of the genetic sequences which encode the genes. Moreover, this argument can be applied to the sequences encoding the different factors, which interact with different enzymes of the blood clotting pathway, and the genetic sequences for encoding different maintence elements or regulatory elements would similarly require different structures, because their functions are different. Lastly, the structural differences between the hemophilias are different, affecting different enzymes, thereby causing different molecular effects, although the macromolecular effect is the same. Hence, each of these species is distinct and do not contribute to a single general inventive concept.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M Kelly whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER